REMARKS

Claims 3 and 5-9 are pending; Claims 1-2, 4 have been cancelled. New claim 10 has been added.

In the Office Action mailed May 29, 2009, claims 3 and 5-9 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 5,698,195 to Le et al. (*"Le"*). Claims 3 and 5-9 have been rejected as allegedly indefinite under 35 U.S.C. § 112, second paragraph. Claims 3 and 5-9 have been rejected as allegedly lacking written description under 35 U.S.C. § 112, first paragraph.

The undersigned attorney and Dr. Oleg I. Epstein, the inventor, had a personal interview with the Examiner on August 14, 2009. The undersigned attorney thanks the Examiner for courtesies extended during the interview.

By this Amendment, Applicant amended claims 3 and 5 and added new claim 10. Support for new claim 10 may be found in the specification and claims as filed. No new matter has been added. Applicant respectfully requests reconsideration and allowance of the pending claims in view of the remarks set forth below.

I. ANTICIPATION REJECTION OVER *LE*

All pending claims have been rejected as allegedly anticipated by *Le*. All pending claims recite a "homeopathically potentized" form of an antibody to tumor necrosis factor alpha (TNF-α). It is undisputed that *Le* does not disclose anything related to homeopathy or homeopathic technology. During the personal interview and in the interview summary, the Examiner asserted that *Le* discloses a "homeopathically potentized form" recited in the rejected claims because certain dilutions of *Le* could result in "homeopathic potentiation or activation." Thus, it appears to be Examiner's position that while *Le* does not expressly disclose homeopathy or homeopathic technology, certain processes of *Le* nevertheless would lead to homeopathic activation and thus *Le* would inherently anticipate the pending claims.

Applicants strongly and respectfully disagree.

A finding of inherent anticipation requires a showing that, while not disclosed explicitly, the prior art composition possesses the properties of the claimed composition. MPEP §2112. *See also Schrieber*, 128 F.3d at 1478. The process established in the law

for evaluating inherent anticipation includes two steps. *Id.* The Examiner must first come forward with a *prima facie* case of inherent anticipation. *Id.* If the Examiner satisfied the burden, the Applicant may rebut the *prima facie* case by making the requisite evidentiary showing. *Id.* To make a *prima facie* case of inherent anticipation, the Examiner must come forth with a scientific rationale or objective evidence tending to show inherency. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Only if the Examiner successfully sets forth the requisite evidence or rationale, then and only then the burden shifts to the patent applicant to come forward with an evidentiary showing to rebut the *prima facie* case of inherent anticipation. *Rijckaert*, 9 F.3d at 1534.

The Examiner did not present evidence or scientific rationale that any process of *Le* would result in "homeopathically potentized" antibodies beyond an unsupported assertion that any dilution would lead to homeopathic activation. Such assertion is manifestly insufficient to satisfy the USPTO's burden of setting forth a *prima facie* case of inherent anticipation under the law. There is simply no reason to believe that such simple dilution would result in homeopathic potentization. If Examiner will continue to make this assertion going forward in the present prosecution, the Examiner is respectfully requested to set forth specific portions of *Le* which the Examiner considers anticipatory and provide some further elaboration. If and only if such identification of relevant portion(s) of *Le* and elaboration of specific reasoning were to be sufficient to meet the burden imposed upon the USPTO under the law, the Applicant would be obligated to come forth with an evidentiary showing that *Le* does not set forth "homeopathically potentized form." At a minimum, such elaboration and identification would enable the Applicant to consider which evidentiary showing would be appropriate.

Notwithstanding the foregoing and while the Applicant considers the evidence already in the file wrapper insufficient to set forth a *prima facie* case of inherency, the Applicant nevertheless sets forth herein additional evidence bearing on the issue raised by the Examiner to advance the prosecution on the merits.

The Examiner's attention is respectfully directed to a Declaration of Dr. Oleg I. Epstein ("*Epstein Declaration*") and a Declaration of Dr. V. N. Nikolayev ("*Nikolayev Declaration*"), both attached herewith. The attached declarations and Exhibit A are now unrebutted evidence in the file wrapper of the present application. Dr. Epstein declared

that the term "homeopathic potentization" has a well-defined meaning in the art. *See Epstein Declaration*, par. 6. While the scope of the term is not limited to specific potentization methodology, the overall state of homeopathic art (*see*, *e.g.*, Exhibit A) provides this term with context. For example, the Exhibit A attached with the *Epstein Declaration* provides examples of various potentization techniques.

The *Epstein Declaration* is supported by the *Nikolayev Declaration*. According to the *Nikolayev Declaration*, the term "homeopathic potentization" is understood as "creating the desired homeopathic potency" through homeopathic technology. *See* par. 7. Dr. Nikolayev is a scientist with long experience in homeopathy and homeopathic technology (*see* par. 2), he is not employed by Dr. Epstein or the company led by Dr. Epstein (*see* par. 3), and his declarations should be accorded an added weight.

After providing evidence that the term "homeopathic potentization" has a well-defined meaning, upon detailed review of *Le*, the *Epstein Declaration* and the *Nikolayev Declaration* unequivocally declare that <u>none of the processes disclosed in *Le* would lead to homeopathic potentization</u>. For example, the *Epstein Declaration* (par. 11) explains that

> While homeopathic potentization can be obtained through various means, the most common form of obtaining potentization is dilution in stages, coupled with external shaking, electromagnetic treatment, etc. None of the process disclosed in Le involve any steps that I as one skilled in the art would expect will lead to homeopathic potentization.

The *Nikolayev Declaration* (par. 8) confirms the conclusion reached by Dr. Epstein. The *Nikolayev Declaration* (par. 9) further declares that "no specific substance disclosed in *Le* is 'homeopathically activated or potentized.'"

Therefore, the evidence currently in the file wrapper establishes a clear line of demarcation between antibodies disclosed and claimed in *Le* and those disclosed and claimed in the present patent application. It is therefore apparent that *Le* does not anticipate claim 3, as amended, and dependent claims 5-10.

Withdrawal of the anticipation rejection is respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. §112

The Examiner rejected all pending claims as allegedly indefinite under 35 U.S.C. §112, second paragraph, asserting that the terms "centesimal homeopathic dilutions," "C50, C200 and C1000 homeopathic dilution," and "C12, C30 and C200 homeopathic dilution," are vague and indefinite because "dilutions are relative terms whose metes and bounds cannot be determined without the original concentration of the initial solution prior to dilution."

Applicants first note that claim 3 does not contain the terms "centesimal homeopathic dilutions," "C50, C200 and C1000 homeopathic dilution," and "C12, C30 and C200 homeopathic dilution." Therefore, the rejection is considered inapplicable to claim 3.

With respect to claims 5-9, the term "centesimal homeopathic dilutions," as well as C50, C200, C100, C12, C30 and C100 with respect to dilutions, have a well defined meaning in the homeopathic art.

"In reviewing a claim for compliance with 35 U.S.C. §112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent [*emphasis added*]." MPEP 2173. Applicant respectfully directs the Examiner to the *Epstein Declaration*, including Exhibit A. Exhibit A is an excerpt from a published English language translation of German Homoeopathic Pharmacopoeia (GHP) (1991), which includes the (i) the title page, (ii) the content page, iii) two pages from the section entitled "Formulations and Presentations," and (iv) a portion of the monograph entitled "Manufacture." In the section of the attached Exhibit A entitled Formulations and Presentations, the GHP teaches:

> Liquid formulations are mother tinctures and solutions, as well as liquid dilutions of these; solid formulations are triturations of these (triturations). Different concentrations of these formulations (degrees of dilution) are obtained by *potentization*.

> *Potentization* in this context is the dilution by stages of solid or liquid formulations by the stated Method.
>
> The letter x [D in German usage] is used to designate dilutions made in a ratio of 1:10, the letter c [C in German usage] dilutions made in a ratio of 1:100.
>
> A figure added to the designatory letters 'x' and 'c' refers to the number of dilution stages [*emphasis in the original*].

In the section entitled "Manufacture," the GHP describes standard homeopathic preparation technologies for various known homeopathic preparations. For each described method, the GHP describes the necessary potentization methodology, including how to make centesimal homeopathic dilutions. It is clear that the meaning of the term "centesimal homeopathic dilutions" as well as C50, C200, C100, C12, C30 and C100 with respect to dilutions was well defined to one skilled in the art at the time of filing of the '651 application. Thus, "centesimal homeopathic dilutions" of the antibodies was clearly in possession of the inventors as of the filing date of the '651 application.

Therefore, the evidence now in the file wrapper clearly establishes that rejected claims 3 and 5-9 are clear to one of ordinary skill in the art. Withdrawal of the indefiniteness rejection is respectfully requested.

The pending claims also have been rejected as allegedly lacking written description under 35 U.S.C. §112, first paragraph. According to the Examiner:

> The claims recite or encompass the term "homeopathically activated form" which is new matter not disclosed in the specification. Applicants argue that the term does not require an *Haec verbis* or *ipsis verbis* disclosure. However, the term is functional claim limitation which is generic to term "potentiated."

Applicant makes reference to Exhibit A attached with the *Epstein Declaration* and the content of the *Epstein Declaration* and *Nikolayev Declaration*. As amended, claim 3 now recites:

> 3. (Currently Amended) A medicament effective in correcting a pathologic immune reaction, said medicament comprising a homeophathically **potentized** ~~**activated**~~ form of at least one monoclonal polyclonal or natural antibody to a recombinant human or heterologous tumor necrosis factor alpha (TNF-α).

Applicants again note that *haec verbis* disclosure is not a pre-requisite for complying with the written description requirement. *See* MPEP § 2163. I. B. The description may be express, implicit, or inherent. *Id.* The key to evaluating compliance with the written description requirement is a determination whether the applicant had possession of the claimed invention based on the content of the application as a whole. *See* MPEP § 2163. II. The outcome of the evaluation depends on whether "the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed." *See* MPEP § 2163.01, *citing In re Gostelli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

The specification describes: (a) preparation of "potentiated" antibodies to TNF-α by homeopathic technology (*e.g.*, at page 2, 3rd and 4th paragraph), (b) administration of the activated or potentiated form of the antibody to TNF-α to patients (*e.g.*, Examples 3 and 4), and (c) biological effects of such administration in an animal model (*e.g.*, Examples 1 and 2). The term "potentised" or "activated" have a well defined meaning in the homeopathic art. Attached with the *Epstein Declaration* is the Exhibit A which is an excerpt from a published English language translation of German Homoeopathic Pharmacopoeia (GHP) (1991). As discussed above, attached Exhibit A describes potentization and standard homeopathic preparation technologies for various known homeopathic preparations. For each described method, the GHP describes the necessary potentization methodology. It is clear from the Exhibit A, together with the specification as a whole (including section identified with specificity) and as supported by the *Epstein Declaration* and *Nikolayev Declaration*, that the meaning of the term "homeopathically potentized" is well defined to one skilled in the art at the time of filing of the '651 application. In combination, these disclosures clearly place "homeopathically potentized form" of the antibodies in possession of the inventors as of the filing date of the '651 application.

Applicants respectfully submit that amended claim 3 and dependent claims 5-10 are fully supported in the application as filed. Withdrawal of the rejection is respectfully requested.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711

Respectfully submitted,

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